

REMARKS/ARGUMENTS

The Office Action mailed August 9, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. Claims 10-35 stand withdrawn from consideration in this application. The claims presented for examination in this application are: claims 1-9 and 36-43.

35 U.S.C. 112 Rejection

In numbered paragraph 12 of the Office Action mailed August 9, 2004, claims 1-8 and 36-43 were rejected under 35 U.S.C. 112; second paragraph, as allegedly being indefinite.

- a) The term "optically encoded" was alleged to be vague and indefinite because it is unclear what constitutes the metes and bounds of "optically encoding" with regard to the step of adding fluorescent labeled antibodies.
- b) The term "optically encoded" was alleged to be vague and indefinite because it is unclear what constitutes the metes and bounds of "optically encoding" with regard to the optically decoding step.
- c) Clarification is allegedly needed between the optically encoded microbeads with a capture ligand and the optically encoded micro beads with bioagent-specific antibodies.
- d) The method step of "providing said optically encoded micobead with a capture ligand" was allegedly confusing.
- e) Claim 8 is allegedly confusing because it is unclear as to the relationship of the optically encoded microbeads with capture ligand of claim 1.
- f) Claim 36 is allegedly vague and indefinite because it is unclear what is an optically encoded microbeads, charged optically encoded microbeads, and optically encoded microbeads with optically encoded shells.

The independent claims have been amended; therefore in effect all of the claims 1-9 and 36-43 presented for examination in this application are amended. The claims 1-9 and 36-43 presented for examination now include the step, "optically decoding said optically encoded microbeads by identifying said optically encoded microbeads and said fluorescent labeled antibodies for detection and measurement of the targeted biological sample."

Applicants submit that the scope of the claimed subject matter can be determined by one having ordinary skill in the art and claims 1-9 and 36-43 presented for examination comply with the requirements of 35 U.S.C. 112, second paragraph. The specification contains sections describing the step and indicating that systems for optically decoding the optically encoded microbeads are available. Relevant portions of Applicants' specification are set out below:

[0008] A multiplex detection system using a Liquid Array is a more flexible and cost-effective format than either the JBPDS or the DNA chips, described above. By use of the Liquid Array, additional assays can be added simply by addition of different color bead sets. Up to 100-plex assay can now be performed using a 10x10 array of microbead sets developed by Luminex Corporation, Austin, TX under U.S. Patent No. 6,057,107 issued May 2, 2000 to J.R. Fulton. Each microbead is individually doped with two fluorescent dyes (orange and red) as indicated in Figure 1, wherein a liquid array shows the absolute intensity of the two dyes (orange and red) as indicated by legend and arrows and which provides a method to uniquely identify each microbead set.

[0011] Luminex Corp. developed the Liquid Array concept of Figures 1-3 to be used in conjunction with a benchtop flow cytometer. Each optically encoded and fluorescently labeled microbead is individually counted for the fraction of a second it passes through the detection system, creating the need for a complex fluidics and optoelectronics package. The Luminex Corp. flow cytometer, therefore, is well suited for laboratory analysis but is neither inexpensive nor compact enough to be used in field or chair-side measurements.

[0012] The present invention which utilizes the liquid array approach of Luminex Corp., as described above, involves a method for constructing a portable pathogen detection system that accomplished on-site multiple detection of targets in biological samples. In the system of the invention, a highly flexible Liquid Array utilizes optically encoded microbeads as the templates for biological assays. The system of this invention basically contains microbead specific reagents, incubation/mixing chambers, a microbead capture array substrate, and an optical measurement and decoding system. Target biological samples are optically labeled and captured on the microbeads, which are in turn captured on an ordered array and optically read.

[004] 4) Optoelectronics for optical assay detection and decoding: The fixed matrix method (i.e., detection of microbeads caught on the disposable capture array) has two major advantages over the Liquid Array approach used by Luminex. The ability to integrate the returned fluorescent signal over longer periods makes inexpensive and compact light sources (LEDs) and detectors (photodiodes) feasible, and detection of the microbead array can occur serially, making incorporation of additional light sources at different wavelengths much easier, thus improving the multiplexing capability of the system.

The optical system consists of the following components: an illustration source, detection electronics, analysis package, and user interface. The simplest types of light sources include light emitting diodes (LEDs), laser, laser diodes, and filament lamps. These sources can be used in conjunction with optical filters, diffraction gratings, prisms, and other optical components to provide a specified spectral component of light. Alternative forms of radiation such as bioluminescence, phosphorescence, and others could also potentially be employed. Although typical fluorophores, require excitation wavelengths in the visible portion of the spectrum (300-700 nm wavelength), other wavelengths in the infrared and ultraviolet portion of the spectrum could also prove useful for illuminating the disposable microbead capture array. The transmitted, reflected, or re-emitted light from the trapped microbeads must then be propagated to an optical apparatus for detection, using photosensitive detectors such as photodiodes or photomultiplier tubes, in combination with some type of spectral and/or spatial filtering. Spatial filtering of the light is possible by either transverse scanning of the disposable

capture array or with two-dimensional detectors such as charge coupling device cameras (CCDs) and video cameras.

Applicants submit that claims 1-9 and 36-43 presented for examination comply with the requirements of 35 U.S.C. 112, second paragraph. The specification contains sections describing the step, "optically decoding said optically encoded microbeads by identifying said optically encoded microbeads and said fluorescent labeled antibodies for detection and measurement of the targeted biological sample." The scope of claims 1-9 and 36-43 presented for examination can be determined by one having ordinary skill in the art. Applicants believe they have provided a full and complete response to the rejection of claims 1-8 and 36-43 under 35 U.S.C. 112, second paragraph, stated in numbered paragraph 12 of the Office Action mailed August 9, 2004.

Allowable Subject Matter

In numbered paragraph 13 of the Office Action mailed August 9, 2004, reasons for allowance were stated. Applicants appreciate this indication of allowable subject matter.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated August 9, 2004 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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